REMARKS

Claims 1-10, 57-75, 77-85, 87, 99 and 100-103 are pending. Claims 76, 88 and 88-98 are cancelled. Support for the Amendment may be found throughout the specification and drawings as filed. Attached hereto is a marked-up version titled "Version with Markings to Show Changes Made."

The request for continued examination filed concurrently with the present preliminary amendment includes an information disclosure statement in which United States Patent 5,266,347, "Antibiotic Biomass Animal Feed Compositions" to King; United States Patent 4,081,527, "Chlortetracycline Compositions" to Armstrong et al; and "Feeds and Feed Additives, Nonruminant Feeds" to Waldroup are included. These references, alone or in combination with any of the previously submitted references do not teach or suggest the present invention. For instance, in Claims 1, 57 and 87, "fermentation solids having an antibiotic activity sufficient to treat an animal" is claimed, which is not taught, shown or suggested in any of the references. Indeed, King even teaches away from the use of an antibiotic biomass, stating that such an antibiotic in a biomass is normally not absorbed or retained within the animal. *See King, Col 6, Lines 30-37.* Additionally, neither the Kemp reference nor the Klothen reference teach or suggest the present claimed invention.

35 U.S.C. §112

The Examiner rejected Claims1-10, 61, 66-75, 87, 99 and 100 as being indefinite. The Applicant respectfully disagrees.

It is well established that the terms in a claim should carry "their ordinary meaning, unless it appears that the inventor used them differently." *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1580, 6 USPQ2d 1557, 1560 (Fed. Cir. 1988), citing *Envirotech Corp. v. Al George, Inc.*, 730 F.2d 753, 759, 221 USPQ 473, 477 (Fed. Cir. 1984) (emphasis added). To determine if a patent uses a term differently from its ordinary meaning the specification and prosecution history should be considered. *ZMI Corp.*, 844 F.2d at 1580, 6 USPQ2d at 1560 (emphasis added). Additionally, even when claim terminology that is not defined in the application is complex, a standard dictionary

may be used to define the claim. *See In re Barr,* 444 F.2d 588, 170 USPQ 330 (C.C.P.A. 1971).

It is respectfully submitted that the Examiner has confused the requirements of §112 with the requirements of §§102 & 103. For instance, the Examiner stated the following:

> Indefinite and relative terms may well be known in the art--they however, permit of wide interpretation--so wide that they permit of anticipation by the prior art, substantially, for instance can refer to function or quantity; it can mean, depending upon the use, 10%, 20%, 50%, or more. *Final Office Action Dated December 4, 2001.*

Therefore, the Examiner seems to be stating that the term may be read broadly so as to be anticipated. However, in such a case, a rejection under §102 is proper (providing a suitable reference is found), and not under §112. The term "substantially" is well understood by a person of ordinary skill in the art as used. Additionally, the term "substantially" is well understood by the courts, such as the Court of Claims and Patent Appeals. Specifically, the Examiner has not responded to the Applicant's argument that "substantially" is a well-known term as understood by the Court of Claims and Patent Appeals, nor has the Examiner shown support for such a statement that would be in contradiction to the submitted cases.

> In rejecting a claim under the second paragraph of 35 U.S.C. 112, it is incumbent on the examiner to establish that one of ordinary skill in the pertinent art, when reading the claims in light of the supporting specification, would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the claims. *See Ex parte Wu*, 10 USPQ 2d 2031, 2033 (P.P.A.I. 1989) citing *In re Moore*, 439 F.2d 1232, 169 U.S.P.Q. 236 (C.C.P.A. 1971).

Therefore, it is respectfully submitted that the terms "substantially," "high resistance," "admixture," "blending," and "low" are definite and particularly point out the claimed invention.

Claims 4 and 5 have been amended as suggested by the Examiner.

Therefore, it is respectfully submitted that the claims are allowable, and withdrawal of the rejection is respectfully requested.

35 U.S.C. §102(e)

The Examiner rejected Claims 1-5, 7-9, 57, 60, 61, 63, 64, 66, 70, 71, 73, 77, 78, 80-82, 87, 99 and 100 under 35 U.S.C. § 102(e) as being anticipated by Kemp, U.S. Pat. No. 5,908,634. The Applicant respectfully disagrees.

Anticipation requires that "the reference must teach every aspect of the claimed invention either explicitly or impliedly." *MPEP* §706.02(a) (emphasis added). Further, "anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1982) (citing Connell v. Sears, Roebuck & Co., 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1984) (emphasis added).

As stated above, Kemp does not teach "*fermentation solids having an antibiotic activity*" nor does Kemp teach such fermentation solids having an activity "*sufficient to treat an animal*" as claimed. Therefore, it is respectfully submitted that a *prima facie* case of anticipation has not been shown by the Examiner, and withdrawal of the rejection is respectfully requested.

35 U.S.C. § 102(b)

The Examiner rejected Claims 1-9, 57-64, 66-74, 77-84, 87, 99 and 100 under 35 U.S.C. § 102(b) as being anticipated by Klothen, U.S. Pat. No. 4,447,421. The Applicant respectfully disagrees.

As claimed in Claims 1, 57 and 87, an animal feed premix and supplement is produced from a broth by reducing a fermentation broth to obtain a fermentation solid. However, in the Klothen reference, a process is disclosed wherein a particulated animal feed is formed by combining a drug with a compressible carrier, followed by blending the mixture, compressing the mixture, and granulating the composition. Specifically required both in the claims and specification of the Klothen reference is the compaction step of the process. In the present invention, as claimed, a substantially dustless animal premix composition is provided without the necessity of the compaction step of the Klothen reference.

Thus, the Klothen reference attempts to overcome the problem of dust by compaction of the premix which is an unneccessary and undesirable step in practicing the present invention, and would result in a structural composition of the product which is different than the present invention. The Klothen reference provides a compacted animal feed which may result in problems that are specifically addressed by the present invention, as shown in the following:

> "Dust Particles that adhere to feed mills or other feed processing equipment or that may be carried away in dust collection system may contain significant quantities of the active ingredient. This may cause the feed mixtures to have a lower concentration of the medicament desired. Dust adherent to the feed processing equipment and dust collected in a dust collection that is recycled in subsequent batches may cause the feed mixtures produced in later batches to have a higher concentration of the active ingredient than desired, or may cause carry over of the drug to feed batches which are not intended to contain the drug. *Application, Page 2.*

Therefore, by utilizing the present invention, a particulate free of cross-contamination may be produced without the contaminating compaction step of the Klothen reference.

Further, the Klothen reference teaches away from the present invention. For example, as stated in the summary of the invention of Klothen reference:

> [O]ther attempts relate to the preparation of wet aggregates followed by granulation and subsequent drying of the granules .... The latter process is generally too costly for this type of application and also, because of the frequent use of water, causes stability problems with many drugs.

Id. at Col. 2, Ln 4-6, 11-14.

In the present invention, a "wet" process may be performed to arrive at a substantially dustless granular feed premix composition without stability problems. For example, referring to Claims 1, 57, 66 and 77, an organism producing an antibiotic is cultured in a fermentation medium to produce a fermentation broth which is then reduced to obtain fermentation solids comprising said antibiotic. Thus, the fermentation solid comprises the antibiotic, wherein in the Klothen reference, an antibiotic is merely added to animal feed and then compacted.

Additionally, nowhere in the Klothen reference is disclosed the step of adding an additional quantity of an antibiotic to a fermentation broth to increase the antibiotic activity of the fermentation broth, as claimed in the present application. By adding an

additional amount of antibiotic, greater levels of an antibiotic may be achieved than through a fermentation process utilized alone. Additionally, even if achieving the desired level of antibiotic activity would not require the additional of additional antibiotic, it may still be preferable to add the additional antibiotic in order to save time and yet achieve the cost reduction of the fermentation process. For example, the fermentation process may show increased activity over the initial stages, but then result in slower fermentation as the levels of the antibiotic increase in the broth. Therefore by utilizing the present invention, a large quantity of antibiotic may be generated in a short amount of time during the periods of greatest production, and then fortify the broth containing the antibiotic with additional amounts of antibiotic, which may be provided from other fermentation processes, *See Page 14, Line 25 to Page 17, Line 3*, to achieve the desired activity.

Moreover, Klothen does not "*fermentation solids having an antibiotic activity*" nor does Klothen teach such fermentation solids having an activity "*sufficient to treat an animal*" as claimed. Therefore, it is respectfully submitted that a *prima facie* case of anticipation has not been shown, and withdrawal of the rejection is respectfully requested.

35 U.S.C. § 103(a)

The Examiner rejected Claims 1-10, 57-75, 87, 99 and 100 under 35 U.S.C. § 103(a) as being unpatenable over Kemp, U.S. Pat. No. 5,908,634 in view of Klothen, U.S. Pat. No. 4,447,421. The Applicants respectfully disagree.

"Obviousness cannot be established by combing the teachings of the prior art ... absent some teaching, suggestion or incentive supporting the combination." *Manarch Knitting Mach. Corp. v. Sulzer Morat GmbH*, 129 F.3d 877, 45 USPQ 1d 1977, 1981-82 (Fed Cir. 1998). The Examiner first asserts Kemp "to provide non compacted granules of premix of non-compacted ingredient," and then asserts Klothen to cure the defects of the reference, such as a fermentation source. As articulated by the Federal Circuit, the question is not whether a combination could be used, as shown in the following excerpt.

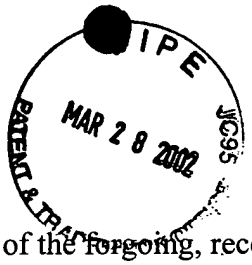
> It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements .... The evidence that the combination was not viewed as technically feasible must be considered, for conventional wisdom that a combination should not be made is evidence of unobviousness. *Arkie Lures, inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 43 USPQ 2d 1294 (Fed. Cir. 1997).

As stated above, Klothen expressly teaches away from the present invention and the use of wet aggregates, "known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness." *United States v. Adams*, 383 U.S. 39, 52, 148 USPQ 479, 484 (1966).

Furthermore, even assuming for the sake of argument that one having ordinary skill in the art would be motivated to make the modification proposed by the Examiner, such a modification would not result in the Applicant's invention. In the present case, the Examiner proposes the modification of a molasses by-product of Kemp with a compaction process of Klothen. Thus, there is no motivation as supplied by the references to a person of ordinary skill in the art to make such a combination. Moreover, the Examiner seems to indicate that no relevance is given to the process by which the components are achieved. However, in Claims 66, 77 and 87, process claims are submitted, which, as the Examiner is well aware, are entitled to being contemplated in the obviousness determination, as shown in the following excerpt:

> [O]bviousness requires that one compare the claim's "subject matter as a whole" with the prior art to which said subject matter pertains." 35 U.S.C. Section 103. The inquiry is thus highly fact-specific by design. This is so "whether the invention be a process for making or a process of using, or some other process." *In re Ochiai*, 71 F.3d 1565, 37 USPQ 2d 1127, 1131 quoting *In re Kuehl*, 475 F.2d 658, 665, 177 USPQ 250, 255 (C.C.P.A. 1973).

Thus, the present invention, as claimed, must be examined as a whole, and withdrawal of the rejection is respectfully requested.



CONCLUSION

In light of the foregoing, reconsideration and allowance of the claims is earnestly solicited.

Respectfully submitted,
Winstrom,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please amend the claims as follows.

1. (Thrice Amended)A substantially dustless animal feed premix composition in solid noncompacted granular form and having a [high] resistance to powdering, said composition comprising a physical admixture of granular fermentation solids comprising an antibiotic, said fermentation solids resulting from reduction of a fermentation broth including a fermentation medium in which an organism was cultured for producing the antibiotic, said fermentation solids having an antibiotic activity sufficient to treat an animal, and further comprising at least one potency standardizer selected from the group consisting of an edible feed material and a mineral product.

4. (Amended) A composition according to claim 1, wherein said antibiotic is selected from the group consisting of amphotericin B, bacitracin, erythromycin, hygromycin B, tetracycline, chlortetracycline, demeclocycline, oxytetracycline, thiostrepton, [or]and tylosin.

5. (Amended) A composition according to claim 4, wherein said antibiotic is selected from the group consisting of tetracycline, chlortetracycline, demeclocycline, and oxytetracycline.

57. (Twice Amended) A particulate, substantially dustless noncompacted animal feed supplement comprising fermentation solids comprising an antibiotic product of a fermentation process, said fermentation solids resulting from reduction of a fermentation broth including a fermentation medium in which an organism was cultured for producing the antibiotic, said fermentation solids having an antibiotic activity sufficient to treat an animal, said animal feed supplement prepared by blending fermentation solids with an edible feed material and a mineral product to produce a mixture thereof.

87. (Twice Amended) A particulate, substantially dustless animal feed supplement comprising fermentation solids comprising an antibiotic product of a fermentation process, said animal feed supplement prepared by:
providing fermentation solids, said fermentation solids having antibiotic activity;
adding an antibiotic to said fermentation solids;
drying said fermentation solids to produce a solid having a low moisture content; and
granulating said dry solid to produce granulated fermentation solids comprising granules having a substantially uniform particle size, said granulated fermentation solids having an antibiotic activity sufficient to treat an animal.

101. (New)A medicated animal supplement for the treatment of animals, said supplement comprising granular fermentation solids including an antibiotic, said fermentation solids resulting from reduction of a fermentation broth including a fermentation medium in which an organism was cultured for producing the antibiotic, said fermentation solids having an antibiotic activity sufficient to treat an animal.

102. (New) The medicated animal supplement as described in claim 101, wherein the fermentation solids include the remnants of the reduced fermentation broth, fermentation medium, remnant of organism which was cultured for producing the antibiotic and the antibiotic.

103. (New) The medicated animal supplement as described in claim 101, wherein the antibiotic activity sufficient to treat an animal includes an antibiotic activity of sufficient level to be at least one of absorbed and retained within the animal.